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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,359

07/21/2006

Rosanne Bonjouklian

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ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

08/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/597,359	Applicant(s) BONJOUKLIAN ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I (i) in the reply filed on Jun 23, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is evidenced that when W is not imidazolyl (elected invention), the compounds are antiproliferative agents (Gwaltney CA132:137378) or synthetic starting material (Zubarovskii CA67:116849). When R²-R³ are taken together to form a ring, the compounds are leukotriene inhibitors (Prous et al. CA145:410660). Therefore, the restriction between Y is CR1 or N and among (i), (ii) and (v)(vi) or (vii) is proper.

The requirement is still deemed proper and is therefore made FINAL.

Based on the election, compounds of formula I wherein Y is CR1, W is (i) or (ii) are prosecuted. Claims 1-5 being drawn to the remaining subject matter are withdrawn from consideration per 37 CFR 1.142(b).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boujouklian et al. US 7,320,995 supplemented with Boujouklian et al. CA140:143142.

See col. 73, example 181-col. 78 example 209+ benimidazolylimdazoles with instant R being H, or SO₂R⁷, R¹ is amino and structural delineation from CA140 (not exhausted listing).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over Boujouklian et al. US 7,320,995.

The examples that anticipates the R is hydrogen compounds have been clearly pointed out supra (see section 2). The difference between the generic scope when R is alkyl or the dependent claim 4 from the anticipatory examples of the '955 is that instead of R is H, the R is methyl. The replacement of a ring hydrogen with a methyl moiety is considered structural prima facie since such homologous replacement is considered within that area of modification within the sphere of teaching embraced by the prior art hydrogen. See In re Wood 199 USPQ 137.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 rejected under 35 U.S.C. 103(a) as being unpatentable over DeNanteuil et al. US 6,040,327.

Determination of the scope and content of the prior art (MPEP §2141.01)

DeNanteuil et al. '327 disclosed therapeutically active compounds of formula I generically embraced the instant claims when X is NR, R2 is substituted imidazol, R1 is linear or branched alkyl or hydroxyl (see col. 1-2). An example drawn to R1 is hydroxyl was exemplified see col. 6, example.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the exemplified species and the instant claims is that the R1 is alkyl was not exemplified. The DeNanteuil '327 reference has however, exemplified variations of R1 corresponding to the broad scope of the description, therefore, has fully enabled the generic scope of the reference.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the DeNanteuil et al. '327 reference would be in possession of the R1 is methyl compounds. The difference between the prior art and the instant claims would be a one methyl addition. The difference of one methyl homologous

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chain would be considered structurally prima facie because decisions on such structural homologue is truly monumental. see *In re Hoch* 166 USPQ 406; *In re Shetty* 195 USPQ 753; *In re Jones* 21 USPQ2d 1941; *In re Dillion* 16 USPQ2d 1897; *In re Grabiak* 226 USPQ 870 etc.

6. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,320,995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to the instant elected scope when R is H or SO₂R⁷ while the instant claims have R being methyl or SO₂R⁷. The homologous nature of structural prima facie between H and methyl has been clearly delineated supra in sections 3 and 4 supra. The decisions on such structural homologue is truly monumental. see *In re Hoch* 166 USPQ 406; *In re Shetty* 195 USPQ 753; *In re Jones* 21 USPQ2d 1941; *In re Dillion* 16 USPQ2d 1897; *In re Grabiak* 226 USPQ 870 etc.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 24, 2009

*/Celia Chang/
Primary Examiner
Art Unit 1625*